

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MERRILL G. DAVIDSON**

I. PREAMBLE

A. Merrill G. Davidson ("Davidson") hereby enters into this Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance with the statutes, regulations, program requirements and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements") by Davidson. Davidson's commitment to promote compliance extends to any and all entities that submit claims for reimbursement to the Federal health care programs or counsels entities that submit claims for reimbursement to the Federal health care programs, and in which Davidson has or gains a direct or indirect ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3) ("Covered Entities"). Further, Davidson shall have additional requirements with respect to any Covered Entity in which Davidson owns more stock than any other investor, provided such stock ownership constitutes a majority interest ("Majority-Owned Covered Entity"). Contemporaneously with this Agreement, Davidson is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

B. Davidson is currently the owner of 100% of Total Parenteral Services of Florida, Inc. ("TPS") stock, a company that has also entered into an integrity agreement with the OIG. As long as Davidson remains the 100 percent owner of TPS, Davidson shall be deemed in compliance with this Agreement if TPS has satisfactorily complied with its integrity agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by Davidson under this Agreement shall be three (3) years from the effective date of this Agreement. The effective date of this Agreement shall be the date on which the final signatory of this Agreement executes this Agreement.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by Davidson pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

Davidson agrees to undertake the following measures to ensure that he maintains the business integrity required of a participant in the Federal health care programs, and that claims submitted for items or services provided by Davidson or under Davidson's control are in compliance with all statutes, regulations, policies, procedures, and guidelines applicable to the programs and with this Agreement.

A. Compliance Contact

Davidson shall be the compliance contact (with the exception of TPS) for purposes of developing and implementing policies, procedures and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, Davidson is responsible for responding to questions and concerns from Majority-Owned Covered Entities and the OIG regarding compliance with the Agreement obligations. Davidson's contact information, including his mailing address, telephone number, and facsimile number shall be included in the Implementation Report. In the event Davidson's contact information changes during the term of this Agreement, Davidson shall notify the OIG, in writing, within 15 days of such a change.

B. Notification to Covered Entities

Within the first 30 days following the effective date of this Agreement, Davidson shall inform any and all Covered Entities with the exception of TPS of Davidson's compliance obligations under this Agreement. Davidson shall also provide each Covered Entity written notice of that entity's potential liability under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 32 U.S.C. § 1320a-7a, and the

provisions for exclusion from the Federal health care programs, 42 U.S.C. §1320a-7, for submitting claims to a Federal health care program for services or products not rendered and under 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") or 42 U.S.C. § 1395nn (the "Stark Law") for participating in the unlawful referral of Federal health care program beneficiaries. The notice shall also detail Davidson's commitment to comply with all Federal health care program requirements in the conduct of his business. Additionally, the notice shall include a means (*i.e.*, telephone number, address, etc.) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in the Implementation Report.

C. Training and Certification

Within 90 days following the effective date of this Agreement and at least once each year thereafter, Davidson agrees that he will receive at least eight hours of training from an individual or individuals with expertise in the relevant subject areas.

At a minimum, the training sessions shall cover the following topics:

1. Federal health care program requirements related to the proper submission of accurate bills for services rendered and/or items provided to Federal health care program patients;
2. The legal sanctions for improper billing or other violations of the Federal health care program requirements;
3. Examples of proper and improper billing practices; and
4. The legal requirements and liabilities associated with the referral of Federal program beneficiaries under the Anti-Kickback Statute and the Stark Law.

Davidson shall annually certify in writing that he has received the required training. The certification shall specify the type of training received and the date received. Davidson shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

D. Notification of Government Investigations or Legal Proceedings

Within 30 days of discovery, Davidson shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Davidson or any related Covered Entity has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Davidson shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

E. Legal Review of Contracts

Davidson shall have an annual review performed by legal counsel of all contracts and working relationships to examine their legal sufficiency. This review will include any independent contractors and commission or non-commissioned contractors or employees. Additionally, Davidson shall specifically examine his contracts and working relationships to prevent any Anti-kickback or Federal health care program violations.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this Agreement, Davidson gains a direct or indirect ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), such that an entity qualifies as a Covered Entity, Davidson shall notify OIG of this fact as soon as possible, but no later than within 30 days of the entity's qualification as a Covered Entity. This notification shall include the location of the new operation(s), telephone number, facsimile number, Medicare provider or supplier number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider or supplier number. All of Davidson's obligations regarding Covered Entities shall extend to such new Covered Entities (e.g., provision of written notice, etc.).

V. REPORTS

A. Implementation Report

Within 120 days after the effective date of this Agreement, Davidson shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This report, known as the "Implementation Report," shall include:

1. Davidson's mailing address, telephone number, and facsimile number;
2. A copy of the notices Davidson provided to each Covered Entity as described in Section III.B;
3. Davidson's written certification that he has received the required training, and copies of the training course materials, as required by Section III.C;
4. A list of all Covered Entities (including locations and mailing addresses), the corresponding name(s) under which each Covered Entity is doing business, the corresponding telephone numbers and facsimile numbers, each Covered Entity's Medicare provider or supplier identification number(s) and the Medicare contractor's name and address that issued each provider identification number; and
5. A certification from Davidson stating that he has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports

Davidson shall submit to OIG Annual Reports with respect to the status of and findings regarding Davidson's compliance activities for each of the three one-year periods beginning on the effective date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Annual Report shall be received by the OIG no later than one year and 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

1. A copy of the notices Davidson provided to each Covered Entity as described in Section III.B;
2. Davidson's written certification that he has received the required training, and copies of the training course materials, as required by Section III.C;

3. A list of all Covered Entities (including locations and mailing addresses), the corresponding name(s) under which each new Covered Entity is doing business, the corresponding telephone numbers and facsimile numbers, each Covered Entity's Medicare provider or supplier identification number(s) and the Medicare contractor's name and address that issued each provider identification number;
4. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.D. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
5. A certification signed by Davidson certifying that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful; and
6. A certification, if applicable, that he has complied with the terms of the CIA between TPS and the OIG that are identical to the terms in this Agreement. Specifically, those identical sections shall be: 1) training and education; 2) notification of government investigations or legal proceedings; and 3) OIG inspection, audit and review rights. Such satisfaction with the CIA between TPS and the OIG will be sufficient for purposes of fulfilling the identical provisions in this Agreement.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

If to the OIG: Civil Recoveries Branch - Compliance Unit
 Office of Counsel to the Inspector General
 Office of Inspector General

U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Telephone (202) 619-2078
Facsimile (202) 205-0604

If to Davidson: Merrill G. Davidson
President, TPS
771 Blackburn Drive
Mobile, AL 33608
Telephone (334) 607-7152
Facsimile (334) 607-0771

Unless otherwise specified, all notifications and reports required by this Agreement may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

The following shall apply to Davidson and to any Covered Entity in which Davidson has a majority ownership interest as previously defined in section I ("Majority-Owned Covered Entity"):

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of TPS's or any Majority-Owned Covered Entity's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of TPS's or any Majority-Owned Covered Entity's locations for the purpose of verifying and evaluating: (a) Davidson's compliance with the terms of this Agreement; and (b) TPS's or the Majority Covered Entity's compliance with the requirements of the Federal health care programs in which he or it participates. The documentation described above shall be made available by Davidson and all Majority-Owned Covered Entities to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of TPS's or any Majority-Owned Covered Entity's employees, contractors, or agents who consent to be interviewed at the individual's place of business

during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Davidson and all his Majority-Owned Covered Entities agree to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Davidson and all his Majority-Owned Covered Entities' employees may elect to be interviewed with or without a representative of Davidson or the Majority-Owned Covered Entity present.

VIII. DOCUMENT AND RECORD RETENTION

Davidson and all Majority-Owned Covered Entities (as defined in Section I, above) shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for four years.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Davidson prior to any release by OIG of information submitted by Davidson pursuant to its obligations under this Agreement and identified upon submission by Davidson as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Davidson shall have the rights set forth at 45 C.F.R. § 5.65(d). Davidson shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Davidson shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Davidson.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Davidson and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Davidson:

- a. Fails to provide the notices to Covered Entities as required in Section III.B; or
- b. Fails to attend the training required by Section III.D. of the Agreement within the time frames required in that section.

2. A Stipulated Penalty of \$750 for each day Davidson or any Majority-Owned Covered Entity fails to grant access to the information or documentation as required in Section VII of this Agreement. (This Stipulated Penalty shall begin to accrue on the date Davidson or the Majority-Owned Covered Entity fails to grant access.)

3. A Stipulated Penalty of \$750 for each day Davidson fails to comply fully and adequately with any obligation of this Agreement. In its notice to Davidson, OIG shall state the specific grounds for its determination that Davidson has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Davidson must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Davidson of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-2 of this section.

B. Timely Written Requests for Extensions

Davidson may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Davidson fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Davidson receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Davidson has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Davidson of: (a) Davidson's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Davidson shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of his corrective actions, and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Davidson elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Davidson cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.a, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Davidson has materially breached this Agreement, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this Agreement

1. *Definition of Material Breach.* A material breach of this Agreement means:

a. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section X.A; or

b. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by Davidson constitutes an independent basis for Davidson's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Davidson has materially breached this Agreement and that exclusion should be imposed, OIG shall notify Davidson of: (a) Davidson's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Davidson shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Davidson is in compliance with the obligations of the Agreement cited by the OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Davidson has begun to take action to cure the material breach; (ii) Davidson is pursuing such action with due diligence; and (iii) Davidson has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Davidson fails to satisfy the requirements of Section X.D.3, OIG may exclude Davidson from participation in the Federal health care programs. OIG will notify Davidson in writing of its determination to exclude Davidson (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement

and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Davidson wishes to apply for reinstatement, Davidson must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Davidson of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Davidson shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Davidson was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Davidson shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Davidson to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Davidson requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:

- a. whether Davidson was in material breach of this Agreement;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that:
 - (i) Davidson had begun to take action to cure the material breach within that period;
 - (ii) Davidson has pursued and is pursuing such action with due diligence; and
 - (iii) Davidson provided to OIG within that period a reasonable timetable for curing the material breach and Davidson has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Davidson, only after a DAB decision in favor of OIG. Davidson's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Davidson upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Davidson may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Davidson agrees to waive his right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Davidson and the OIG agree as follows:

1. This Agreement shall be binding on the successors, assigns and transferees of Davidson and any Majority Covered Entity;

2. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
3. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;
4. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

MERRILL G. DAVIDSON

8/10/01
Date

Merrill G. Davidson
Merrill G. Davidson
771 Blackburn Drive
Mobile, AL 33608

8/13/02
Date

Jeffrey S. Baird, Esq.
Jeffrey S. Baird, Esq.
Brown & Fortunato, P.C.,
906 S. Fillmore
Amarillo, TX 79105

8/13/01
Date

Darrel J. Scott, Esq.
Darrel J. Scott, Esq.
Brown & Fortunato, P.C.
906 S. Fillmore
Amarillo, TX 79105

**OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES**

8/27/01
Date

Lewis Morris, Esquire
Lewis Morris, Esquire
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human
Services